

CLAIMS

1. A heat-sensitive composition in liquid form, containing
 - a hydrophobic organic liquid,
 - 5 - an organogelling substance, the molecules of which have the capacity to bind together via bonds of low energy, and
 - a bioactive substance,which changes to the organogel form when it comes into contact with a physiological fluid, during its administration to an animal body, in particular man.
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2. The composition according to Claim 1, wherein the organogel is formed by cooling the site of application of the said composition.
3. The composition according to Claim 1, further containing a hydrophilic
15 organic solvent capable of creating weak bonds with the organogelling substance, and wherein the organogel forms by diffusion of said hydrophilic organic solvent into the aqueous medium.
4. The composition according to Claim 1, wherein said organogel has a
20 transition temperature from the liquid state to the gel state which is lower than the temperature of the site of application, and a transition temperature from the gel state to the liquid state that is higher than the body temperature.
5. The composition according to Claim 4, wherein said organogel has a
25 transition temperature from the liquid state to the gel state of less than 30°C and a transition temperature from the gel state to the liquid state of greater than +35°C.
6. The composition according to Claim 3, wherein the proportion of the
30 hydrophilic organic solvent is less than 60% by weight of said composition.

7. The composition according to Claim 6, wherein the proportion of the hydrophilic organic solvent is less than 20% by weight of the said composition.

5 8. The composition according to Claim 3, wherein said hydrophilic organic solvent is selected from the group consisting of ethanol, glycerol, benzyl alcohol, propylene glycol, N-methylpyrrolidone dimethyl sulphoxide (DMSO), poly(ethylene) glycol of low molecular weight, chlorobutanol, furfural, N,N-dimethylacetamide, glycerol formal, isopropylideneglycerol, ethyl lactate, acetic acid and lactic acid.

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9. The composition according to Claim 8, wherein said hydrophilic organic solvent is ethanol.

15 10. The composition according to Claim 1, wherein said hydrophobic organic liquid is selected from the group consisting of plant oils, triglycerides, semi-synthetic oils and water-immiscible organic solvents.

20 11. The composition according to Claim 10, wherein said hydrophobic organic liquid is selected from the group consisting of soybean oil, squalene, benzyl benzoate, a triglyceride and a mixture of benzyl benzoate and benzyl alcohol.

25 12. The composition according to claim 10 or claim 11, wherein said hydrophobic organic liquid is a mixture of different hydrophobic organic solvents.

13. The composition according to claim 11, wherein said hydrophobic organic liquid is a mixture of soybean oil and ethyl oleate.

30 14. The composition according to Claim 1, wherein said biologically active substance is selected from the group consisting of proteins, peptides,

amino acids, vitamins, nucleic acids and oligonucleotides.

15 **15.** The composition according to Claim 14, wherein said biologically active substance is selected from the group consisting of morphine, α -interferon, β -interferon, somatostatin, heparin, interleukins, erythropoietin, calcitonin, human growth hormone, thyrotrope hormone and Leuprolide.

10 **16.** The composition according to Claim 1, wherein the organogelling substance represents between 0.5% and 50% by weight relative to the total weight of the said composition.

15 **17.** The composition according to Claim 1, wherein the organogelling substance is a molecule of low molecular weight with acid, alcohol or amine end groups.

15 **18.** The composition according to Claim 17, wherein the organogelling substance is an amino acid derivative.

20 **19.** The composition according to Claim 18, wherein the organogelling substance is an alanine ester derivative.

20 **20.** The composition according to Claim 19, wherein said organogelling substance is N-lauroyl-L-alanine methyl ester or N-lauroyl-L-alanine ethyl ester.

25 **21.** The composition according to Claim 19, wherein said organogelling substance is N-stearoyl-L-alanine methyl ester or N-stearoyl-L-alanine ethyl ester.

30 **22.** An organogel formed from the composition according to Claim 1, which is capable of remaining stable in gelled form between the temperature of application and the gel/liquid transition temperature of the said composition.

23. A method for administering a bioactive substance to a subject, comprising the injection of the composition according to claim 1 into the body of said subject via the extravascular parenteral route, the intraocular route or the vaginal route, to an open wound or during surgery.

24. The method according to claim 23, wherein said composition is injected into the body of said subject via the subcutaneous route, the intradermal route, the intraperitoneal route or the intramuscular route.

25. A use of the composition according to Claim 1 as a vehicle for the sustained release of bioactive substance(s) into the body.

26. A process for preparing a composition according to Claim 1, wherein the bioactive substance, optionally in aqueous solution, is added to the mixture consisting of the organogelling substance and the hydrophobic organic liquid.

27. A process for preparing a composition according to Claim 3, comprising the steps consisting of :

- dissolving the organogelling substance in the hydrophilic organic solvent ; and then
- incorporating the bioactive substance and the hydrophobic organic liquid.

28. The process according to Claim 27, wherein an aqueous solution of the said substance is dispersed with stirring into the organic phase consisting of the organogelling substance and the hydrophilic organic solvent, when the bioactive substance is sparingly soluble or insoluble in the organic phase.